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## Clinical Protocols – V.7.6.18

## I. Ventilator Management Guidelines

### A. Monitoring

1. All subjects require an arterial line and $SpO_2$ monitoring. Subjects supported on CMV also require $ETCO_2$ monitoring. Noninvasive data are recorded at least Q6H.

2. PICUs may continue using near-infrared spectroscopy (NIRS), transcutaneous gas monitoring, and volumetric capnography (CMV groups) if considered usual care.

### B. Oxygenation and Ventilation Goals (all groups)

1. During the acute phase, the goal is adequate oxygenation and ventilation:
    a. Oxygenation: Pulse Oximeter Oxygen Saturation ($SpO_2$) 88-92%[1]
    b. Ventilation: pH $\geq$ 7.15 and $\leq$ 7.30 (irrelevant of $PaCO_2$)[2]
    c. As the patient's clinical condition improves and criteria for extubation readiness testing (ERT) are met, oxygenation and ventilation parameters are normalized, i.e., $SpO_2$ <98% and pH <7.45.

2. Arterial blood gases and chest radiographs are obtained per the discretion of the clinical team. If lung overinflation is present on CXR (i.e., diaphragms flat and/or depressed below the $10^{th}$ posterior rib) consider decreasing mean airway pressure by 2 cm $H_2O$.

3. Neuromuscular blockade (NMB) is administered for the first 24H post enrollment. After the first 24H, NMB is administered per the discretion of the clinical team.

4. Ventilator disconnects: lung volume is re-established after all ventilator disconnects based on the mode of mechanical ventilation as described below (i.e., PEEP or mPaw titration).

[1] When $SpO_2$ is used to assess arterial oxygenation, the following measures will be taken to improve accuracy: $SpO_2$ sensor will be checked to ensure optimal position, cleanliness, and consistent readings with satisfactory waveforms; no position changes or endobronchial suctioning for $\geq$ 10 minutes; no invasive procedures or ventilator changes for $\geq$ 30 minutes. $SpO_2$ will be observed for a minimum of 1 minute, and a representative value will be recorded on the appropriate source-document flowsheet.

[2] Use of cuffed/uncuffed ETTs will be documented.

## C. Strategy: Conventional Mechanical Ventilation (CMV)

**Goal:** Lung protective ventilation using ventilatory parameters and approaches consistent with those recommended by the Pediatric Acute Lung Injury Consensus Conference (PALICC).

1. **Initiating CMV**
   a. Ventilator modes include synchronized intermittent mandatory ventilation [SIMV] or assist control [AC]); Pressure Control Ventilation (PCV) or Pressure Regulated Volume Control (PRVC or equivalent)
   b. Monitor exhaled Vt ($Vt_e$) and percent ETT leak at the airway.[3]
   c. Suction the patient.
   d. Administer neuromuscular blockade (required for the first 24 hours).

2. **Initial settings CMV**
   a. **Tidal volume (Vt) or Peak Inspiratory Pressure (PIP):**
      1) Set to obtain $Vt_e$[4] 5-7 ml/kg (ideal body weight [IBW][5])
      2) Goal PIP ≤ 28 cm $H_2O$ (may allow up to 32 cm $H_2O$ for patients with poor chest wall compliance)
   b. **Inspiratory Time:** Set based on patient age[6] and disease condition.
      1) Rate adjusted to maintain pH with the target range. Assess flow-time scalar to assess for appropriate inspiratory time.
      2) I:E ratio: maximum 1:1
   c. **Rate:** Titrate based on age and respiratory condition to maintain pH within prescribed goals.
   d. **Pressure Support (PS):**
      1) Pressure support set to maintain spontaneous $Vt_e$ 5-7 mL/kg IBW
      2) Minimal PS (calculated to overcome endotracheal tube [ETT] resistance): 10 cm $H_2O$ for ETT 3-3.5 mm, 8 cm $H_2O$ for ETT 4-4.5 mm, and 6 cm $H_2O$ for ETT ≥ 5 mm
   e. **Fraction of inspired oxygen ($FiO_2$):** As necessary to achieve $SpO_2$ 88-92%
   f. **Positive End-expiratory Pressure (PEEP):**
      1) Lung recruitment maneuver to determine optimal PEEP:
         Step 1: While maintaining the pressure above PEEP,[7] increase PEEP by 2 cm $H_2O$ every 5 minutes while observing $SpO_2$ and dynamic compliance ($C_{dyn}$).
         Step 2: PEEP should be increased until no further improvement in $SpO_2$ or $C_{dyn}$ is noted or systolic blood pressure starts to decrease ($PEEP_{max}$). If during recruitment, $SpO_2$ > 97%, then reduce the $FiO_2$ and continue recruitment maneuver.

[3] Use a proximal away sensor or Philips NM3™ monitor (or equivalent) at the ETT.
[4] Exhaled Vt is continuously monitored and documented every 6 hours.
[5] IBW (as predicted from height): See chart for <178 cm males and <164 females; If male height is >178 cm than IBW (kg) = 50 + 2.3(height in inches - 60); If females height is >164 cm than IBW (kg) = 45.5 + 2.3(height in inches - 60). [To convert inches to centimeters multiply inches times 2.54; to convert centimeters to inches multiply centimeters times 0.4]
[6] 0-1 year: 0.4-0.65 sec; 1-2 years: 0.5-0.7 sec; 2-8 years: 0.6-0.9 sec; >8 years: 0.7-1.2 sec
[7] Do not change the pressure above PEEP. We will tolerate PIP > 28 cmH2O during the lung recruitment maneuver.

Step 3: Once $PEEP_{max}$ is found, decrease PEEP by 2 cm $H_2O$ every 5 minutes until $SpO_2$ decreases ($PEEP_{derecruitment}$) while observing $C_{dyn}$ compliance.
Step 4: Re-recruit: Increase PEEP to $PEEP_{max}$ (as determined above) for 1-2 minutes (as clinically tolerated).
Step 5: Set PEEP at 2 cm $H_2O$ above $PEEP_{derecruitment}$.

**3. Ongoing CMV support**

a. **Reassess the patient and fine-tune ventilator settings <u>at least</u> every 6 hours:** If measured Vt, $SpO_2$, and/or pH are not within the target range, then ventilator adjustments are made and the patient is reassessed within 30 minutes. Changes in more than one ventilator setting may be performed simultaneously.

b. **Titrate $Vt_e$ and PIP:** Maintain $Vt_e$ 5-7 ml/kg IBW. Exhaled Vt as low as 3 ml/kg for severe PARDS (OI > 16) is allowed to maintain PIP ≤ 28 cm $H_2O$ (may allow up to 32 cm $H_2O$ for patients with poor chest wall compliance).

c. **Titrate Respiratory Rate:** Goal is to achieve alveolar ventilation (based on pH goal) using Vt within goal range at the lowest respiratory rate.

d. **PEEP/$FiO_2$** --
**If a patient's PEEP/$FiO_2$ is not compatible with the PEEP/$FiO_2$ table** (e.g., immediately after enrollment or after urgent changes in $FiO_2$ or PEEP in response to desaturation, hypotension, etc.), either PEEP or $FiO_2$ (or both) are adjusted at 5-15 minute intervals until the PEEP/$FiO_2$ is compatible with the grid.

**Titrate per PEEP-$FiO_2$ grid at least every 12 hours.**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **$FiO_2$** | .30 | .40 | .40 | .40 | .50 | .50 | .60 |
| **PEEP** | 5 | 5 | 8 | 10 | 10 | 12 | 12 |
| | | | | | | | |
| **$FiO_2$** | .60 | .70 | .70 | .80 | .80 | | |
| **PEEP** | 14 | 14 | 16 | 16 | 16*-18 | | |

*PEEP of 16 cm $H_2O$ in subjects <1 year of age

Decrease the $FiO_2$ level to maintain SpO2 88-92% then assess if patient is on PEEP level that corresponds with that FiO2. If not, increase/decrease PEEP to keep patient on the grid (vertical pair).

**4. Escalation of Support**

a. Brief periods (≤ 10 min) of $SpO_2$ < 85% or > 92% may be tolerated without making changes in PEEP or $FiO_2$. $FiO_2$ = 1.0 may be used for brief intervals (<10 min) of transient desaturation or to prevent desaturation during treatments, such as suctioning or position changes.

a. **OXYGENATION:** If $SpO_2$ < 85% for more than 10 minutes

1. In the event of any abrupt clinical changes, assess for pneumothorax and obstructed/dislodged ETT.

2. Perform lung recruitment maneuver
   Step 1: Record start PEEP ($PEEP_{start}$)
   Step 2: Increase PEEP by 2 cm $H_2O$ every 5 minutes and observe $SpO_2$
   Step 3: Record PEEP at which $SpO_2$ starts to increase ($PEEP_{recruitment}$)
   Step 4: Continue to increase PEEP as until $SpO_2$ no longer increases or systolic blood pressure starts to decrease (record as $PEEP_{hyperinflation}$).[8] If during recruitment $SpO_2$ > 97%, then first reduce the $FiO_2$ and continue recruitment.
   Step 5: Once $PEEP_{hyperinflation}$ is determined, decrease mPaw by 2 cm $H_2O$ every 5 minutes and observe $SpO_2$.
   Step 6: Record the PEEP at which the $SpO_2$ starts to decrease by more than 2 percentage points ($PEEP_{derecruitment}$). At this point, stop decreasing PEEP.
   Step 7: Increase PEEP to $PEEP_{hyperinflation}$ for 1-2 minutes, then decrease PEEP to 2 cm $H_2O$ above $PEEP_{derecruitment}$

3. If $Vt_e$ < 5-7 mL/kg and PIP ≤ 28 cm $H_2O$, increase $Vt_e$ to 5-7 mL/kg.

4. If $Vt_e$ within range and/or PIP > 28 cm $H_2O$, assess for overdistension (e.g., increase in $PaCO_2$ with a patent airway). If present, perform PEEP titration as described above starting at Step 5 (use current PEEP as $PEEP_{hyperinflation}$).

b. **VENTILATION**: If primary respiratory acidemia (pH < 7.15) is present:
   Step 1: Increase ventilator rate in increments of 2-4 bpm until pH > 7.15 unless evidence exists for air trapping based on airway graphics. Do not exceed I:E 1:1. Ensure inspiratory time within range indicated in Table.
   Step 2: If Vt < 8 mL/kg, then increase Vt incrementally to 8 mL/kg (while maintaining pressure limitation).

**5. Failed CMV**
Four-hour pattern of either:
   a. Persistent hypoxia ($SaO_2$<85%) with $FiO_2$ 1.0 and max PEEP per grid (16 cm $H_2O$ for < 1 year of age; 18 cm $H_2O$ for ≥ 1 year of age).
   b. Persistent hypoventilation (pH <7.15) with PIP > 32 cm $H_2O$ and a respiratory rate that does not cause intrinsic PEEP (i.e., air trapping)

**6. Weaning CMV –** As the patient's clinical condition improves and criteria for extubation readiness testing (ERT) are met, oxygenation and ventilation parameters are normalized, i.e., $SpO_2$ <98% and pH <7.45
   a. Decrease settings as clinically indicated
   b. If $SpO_2$ > 92% and Vt = 4-7 mL/Kg: Decrease set PEEP and/or $FiO_2$ in tandem using the PEEP/$FiO_2$ grid, while maintaining Vt = 5-7 mL/Kg and ≤ 28 cm $H_2O$.
   c. If over ventilating such that pH ≥ 7.30[9]

[8] Consider 5 mL/kg fluid bolus if transient and gentle pressure on the liver bed improves saturation.

[9] Note that oxygenation and ventilation are not independent. If at any time decreasing ventilator pressure results in decreased oxygenation, maintain the same PIP or Vt and decrease the rate incrementally to achieve increase in $PaCO_2$.

Step 1: If Vt = 4-7 mL/kg: Incrementally decrease ventilator rate by 2-4 bpm while maintaining spontaneous respiratory rate within physiologic range.[10,11]
Step 2: If Vt = 4-7 mL/kg and good spontaneous effort: may consider Pressure Support Ventilation to maintain spontaneous Vt at 4-8 mL/kg. (Minimal PS per ETT size[12]).

d. If at any time PIP above range, attempt to wean while maintaining Vt 4-7 mL/kg and pH > 7.15.

[10] Spontaneous RR goal: <6 months 20-60; 6 mo-2 yrs 15-45; 2-5 yrs 15-40; >5 yrs 10-35.
[11] Increased RR can be from anxiety. May need to increase sedation or if anxiety appears to be from excessive work of breathing, then increase PS 2 cm $H_2O$ (if Vt <6 mL/kg) or increase the ventilator rate until RR is within range. If RR is below range and if the patient is over sedated, then decrease sedation/analgesia.
[12] Minimal PS (calculated to overcome the resistance of the ETT): 10 cm $H_2O$ if 3-3.5 mm ETT; 8 cm $H_2O$ if 4-4.5 mm ETT; and 6 cm $H_2O$ if $\geq$ 5 mm ETT.

## D. Strategy: High Frequency Oscillatory Ventilation (HFOV)

**Goal:** The HFOV strategy is based on physiologic principles of gas delivery. To optimize the high-frequency approach, high rates (> 8 Hz) will be used knowing that increased amplitudes will be required for adequate ventilation. Given the known attenuation of pressure amplitude across the endotracheal tube and along the natural airways, pressure amplitude and tidal volume delivery will remain within typical parameters for HFOV at the alveolar level.

1. **Initiating HFOV**
   a. Ventilator: 3100A if subject weight < 35 kg, 3100B if subject weight ≥ 35 kg. Alternate devices with similar gas exchange mechanisms (e.g., active exhalation) may be used once approved by the CCC.
   b. If part of usual care, correlate transcutaneous $CO_2$ monitoring with an arterial blood gas.
   c. Suction the patient.
   d. Administer neuromuscular blockade (required for the first 24 hours).
   e. Consider a fluid bolus (5 mL/kg) if concerned about hemodynamic instability.

2. **Initial Settings HFOV**
   a. **$FiO_2$**: As necessary to achieve $SpO_2$ 88-92%
   b. **Frequency** at 8-12 Hz.
   c. **Amplitude** (delta-P) 60-90[13]
   d. **Mean Airway Pressure** (mPaw)
      1) Set the initial mPaw 5-6 cm $H_2O$ above the current CMV monitored value. May use a smaller mPaw increase if airleak is present.
      2) Perform a mPaw recruitment maneuver:
         Step 1: Record start mPaw ($mPaw_{start}$)
         Step 2: Increase mPaw by 2 cm $H_2O$ every 5 minutes and observe $SpO_2$
         Step 3: Record mPaw at which $SpO_2$ starts to increase ($mPaw_{recruitment}$)
         Step 4: Continue to increase mPaw as until $SpO_2$ no longer increases or systolic blood pressure starts to decrease (record as $mPaw_{hyperinflation}$).[14] If during recruitment $SpO_2$ > 97%, then first reduce the $FiO_2$ and continue recruitment.
         Step 5: Once $mPaw_{hyperinflation}$ is determined, decrease mPaw by 2 cm $H_2O$ every 5 minutes and observe $SpO_2$
         Step 6: Record the mPaw at which the $SpO_2$ starts to decrease by more than 2 percentage points ($mPaw_{derecruitment}$). At this point, stop decreasing mPaw.
         Step 7: Increase mPaw to $mPaw_{hyperinflation}$ for 1-2 minutes, then decrease mPaw to 2 cm $H_2O$ above $mPaw_{derecruitment}$
      3) Maintain mPaw at this setting until $FiO_2$ is weaned to ≤ 0.60 – wean $FiO_2$ when at goal $SpO_2$ for > 2 hours
   **e. Inspiratory Time**
      1) Initially set at 33%
      2) When amplitude is maximized and frequency is minimized (8 Hz), increase inspiratory time to 40% (and then 50%, if needed)
   **f. Bias Flow**

[13] Increased amplitude is required to provide adequate tidal volume for ventilation given the high starting frequencies.
[14] Consider 5 mL/kg fluid bolus if transient and gentle pressure on the liver bed improves saturation.

1) Initial settings per patient age:
   < 1 year of age: 15-25 L/min
   1 -8 years of age: 15-30 L/min [15]
   8 years of age: 25-40 L/min
2) Consider increasing bias flow if frequency is minimized at 8 Hz, mPaw is set at maximum, and/or patient has significant spontaneous respiratory effort.

**3. Ongoing HFOV support**

a. Reassess patient and fine-tune ventilator settings <u>at least</u> every 6 hours. If measured $SpO_2$ and/or pH are not within the target range, then ventilator adjustments are made and the patient is reassessed within 30 minutes. Changes in more than one ventilator setting may be performed simultaneously.

b. **Titrating mPaw**
**mPaw maneuver** – Performed every 12 hours
Step 1: Record the start mPaw ($mPaw_{start}$)
Step 2: Decrease mPaw by 2 cm $H_2O$ every 5 minutes and observe $SpO_2$
Step 3: Record the mPaw at which the $SpO_2$ starts to decrease by more than 2 percentage points (this point is called $mPaw_{derecruitment}$). At this point, stop decreasing mPaw.
Step 4: Increase mPaw to either $mPaw_{start}$ or by 5-8 cm $H_2O$ (whichever is greater) for 2 minutes
Step 5: Decrease mPaw to 2 cm $H_2O$ above $mPaw_{derecruitment}$
Step 6: 1 hour after challenge, obtain ABG and titrate Frequency/Power (see below)
Between mPaw maneuvers, $FiO_2$ may be gradually weaned to a minimum of 0.40 and/or mPaw may be decreased by 2 cm $H_2O$ to maintain $SpO_2$ at goal.

**c. Titrating $FiO_2$**
If $SpO_2 \geq 92\%$ and $FiO_2 > 0.60$, reduce $FiO_2$ by 0.10 until $FiO_2$ 0.60

**d. Titrating Frequency and Power**
Goal is highest frequency that achieves adequate alveolar ventilation.
a) Titration is performed, <u>at least</u>, every 6 hours
b) If the pH is too high (> 7.30)
   Step 1: Increase the frequency by 0.5-1 Hz (max 15 Hz)
   Step 2: If the frequency is 12-15 Hz, decrease the power by 10%

e. **If difficulty ventilating,** consider deflating ETT cuff (while maintaining current mPaw) to augment expiratory gas flow.

**4. Escalation of Support**

a. Brief periods ($\leq$ 10 min) of $SpO_2 < 85\%$ or > 92% may be tolerated without making changes in mPaw or $FiO_2$. $FiO_2 = 1.0$ may be used for brief intervals (<10 min) of transient desaturation or to prevent desaturation during treatments, such as tracheobronchial suctioning or position changes.

b. **OXYGENATION**: If $SpO_2 < 85\%$ for more than 10 minutes

[15] Positioning – ventilation sequence: Position the patient before the mPaw procedure

1. Assess for overdistension (e.g., increase in $PaCO_2$ with a patent airway). If present, perform mPaw challenge as described above. Also, assess for occluded or dislodged ETT.

2. If the $FiO_2$ is $\leq$ 0.50:
   Step 1: If no response to mPaw challenge, increase $FiO_2$ to max 0.50 and observe effect.
   Step 2: If no response, increase mPaw by 2 cm $H_2O$ every 5 minutes until there is no further increase in $SpO_2$. Note the mPaw at which the $SpO_2$ starts to increase ($mPaw_{opening}$). If the $SpO_2$ > 97%, reduce $FiO_2$ to get $SpO_2$ < 97% and continue increasing mPaw until there is no further increase in $SpO_2$. Try to reduce the $FiO_2$ to 0.50.
   Step 3: reduce mPaw by 2 cm $H_2O$ every 5 minutes. Note the point at which the $SpO_2$ decreases again ($mPaw_{derecruitment}$)
   Step 4: Increase mPaw for 2 minutes to $mPaw_{opening}$ or an increase of 5-8 cm $H_2O$, whichever is greater
   Step 5: Decrease mPaw to 2 cm $H_2O$ above $mPaw_{derecruitment}$

c. **VENTILATION**: If primary respiratory acidemia (pH < 7.15) is present:
   Step 1: decrease the frequency by 0.5-1 Hz (minimum frequency of 8 Hz).
   Step 2: if the frequency is 8 Hz, increase the inspiratory time to 40-50%.
   Step 3: if the power is not at 10, increase the power by 10%.

**5. Failed HFOV**

Four-hour pattern of either:
   a. Persistent hypoxia ($SaO_2$<85%) at $FiO_2$ 1.0 and mPaw > 35 cm $H_2O$
   b. Persistent hypoventilation (pH <7.15) with max power/amplitude at a frequency < 8 Hz

**6. Conversion to conventional ventilation**

Conversion to conventional ventilation is mandated when mPaw 15-20 cm $H_2O$ and $FiO_2$ < 0.50. Extubation from HFOV will be considered a protocol deviation.

## II. Suctioning and Re-recruitment (all groups)

A. For safety, the patency of the ETT is assessed Q12H by ETT suctioning.[16]

B. Routine suctioning is not recommended.

C. Consider suctioning with unexplained, rapid increases in $PaCO_2$ and/or decrease in chest movement or, for example, when there is an apparent "saw" pattern visible on the flow – time scalar when on CMV.[17] Care must be taken to maintain lung volumes during suctioning. Significant reductions in $SpO_2$ <85% after suctioning are managed with re-establishing lung volume per mode of mechanical ventilation utilized. Ventilation should be suspended during maneuver (as clinically tolerated) to avoid excessive peak airway pressure.

[16] Perform prior to recruitment maneuver.

[17] There are no data to support specific recommendations on tracheobronchial suctioning technique. No attempt will be made to standardize suctioning practices across study sites, although closed suctioning is recommended per PALICC guidelines. Saline or no saline instillation can be used per study unit routine. Technique will be captured on CRFs.

## III. Daily Test for Patient Readiness for Extubation (all groups after 1st 24H)

A. Every day at 07:00 ± 2H[18-19] the patient is assessed for the following:
- Spontaneous breathing
- Oxygenation Index < 6
- Decrease and/or plateau in ventilator support over the previous 12 hours

If these criteria are present, then the patient is tested for readiness for extubation.

B. Daily Test
1. If $FiO_2$ > 0.5, decrease $FiO_2$ to 0.5[20]
2. If PEEP is > 5 cm $H_2O$, decrease PEEP to 5 cm $H_2O$.
3. Evaluate $SpO_2$ after the above changes
    a. If $SpO_2 \geq 95\%$, change mode to PSV with set PS min based on size of ETT
        1. 10 cm $H_2O$ if ETT 3-3.5 mm
        2. 8 cm $H_2O$ if ETT 4-4.5 mm
        3. 6 cm $H_2O$ if ETT ≥ 5 mm
    b. Monitor $SpO_2$, exhaled Vt, and RR

C. Ready for extubation
1. The patient is potentially ready for extubation (from a pulmonary perspective) if all 3 of the following are present for ≥ 2 hours:
    a. $SpO_2 \geq 95\%$ with $FiO_2 \leq 0.5$ and PEEP ≤ 5 cm $H_2O$
    b. Exhaled Vt ≥ 5 mL/kg
    c. Respiratory rate within respiratory rate goal of age:
        i. <6 months 20-60; 6 mo - 2 yrs 15-45; 2 - 5 yrs 15 - 40; > 5 yrs 10-35
2. If the patient does not meet the above criteria, then return to the pre-test ventilator settings and re-test at 1600 ± 2H.
3. If the patient does not meet the above criteria because of excessive sedation, the care team may elect to wean the patient's sedation (per the sedation protocol) and retest the patient after the wean. If the patient does not meet the criteria at 1600 ± 2H, they are returned to their pre-test ventilator settings and re-tested the following morning.
4. If they meet the above criteria, then the medical team is notified that the patient is ready (from a pulmonary perspective) for unassisted breathing.
5. Extubation may be delayed for the following non-pulmonary reasons:[21]
    - Neurological unresponsiveness and inability to protect one's airway
    - Inaudible leak around an uncuffed/deflated cuff ETT[22]
    - Scheduled test/procedure that requires deep sedation/anesthesia

D. Extubation Guidelines
1. May extubate to $FiO_2$ higher than on ventilator, then wean $FiO_2$ every two hours to room air to maintain $SpO_2$ >92%.

[18] If a patient procedure, test, or other extenuating circumstance prevents assessment for these criteria between 07:00 ± 2H then the test can be delayed up to 4 hours.
[19] For prone positioned patients, the one hour post-supine ABG is used for OI calculation.
[20] Stop feeding per institutional standard
[21] Should extubation be delayed, the reason for the delay will be recorded on data sheet.
[22] In this case, the care team by elect to prescribe dexamethasone for 24-48 hours.

2. If patient develops respiratory distress after extubation and if stridor is present may consider dexamethasone IV. ± racemic epinephrine treatment Q15 minutes x 2 (1-2 years 0.25 mL or >2 years 0.5 mL).
3. If stridor is not present, may consider non-invasive ventilation or high-flow nasal canula if patient is alert, cooperative and able to protect their airway.[23]
4. Should reintubation be required within 24H, cause and date/time is recorded on data sheet. If reintubation is necessary, return to the ventilator algorithm.

[23] Use of assisted ventilation, invasive or non-invasive, will be considered an extubation failure.

## IV. Positional Therapy Protocol

### A. Both Groups

1. Positioning – ventilation sequence: Enrolled subjects will be placed in their randomized position first then transitioned to their randomized mode of mechanical ventilation.
2. Standard beds, per PICU's routine, will be used. The use of low air loss beds is not recommended unless the patient cannot be turned every 2 hours.
3. The head of the bed will be elevated at least 15 degrees.
4. When supine, positioning includes a cyclic rotation from full supine to right lateral/supine to full supine to left lateral/supine to full supine. If the care team believes that a subject cannot tolerate full turns than half turns (listing)[24] will be made every 2 hours to prevent the development of pressure injuries.
5. When supine, a draw sheet will be placed under the patient to facilitate patient turns every two hours. The patient's occiput will be cushioned using pressure-relieving materials (pillow, jell pillow, or similar). The patient's heels are elevated off the bed using an appropriate size pillow placed under the patient's lower legs. Side positioning will be maintained using a soft wedge. Only pressure relieving material will be placed under the patient (no rolled blankets, densely filled stuffed animals, etc.). The integrity of the patient's ear is verified whenever they are positioned on their side.

### B. Supine Group

1. Patients assigned to the supine group will remain in supine.
2. If hypoxia ($SaO_2$<85%) is persistent, may want to consider performing a respiratory recruitment maneuver (per ventilation mode) to increase the amount of aerated lung.

3. **Failed Supine:** Four-hour pattern of either:
   a. Persistent hypoxia ($SaO_2$<85%)
      a. CMV: with $FiO_2$ 1.0 and max PEEP per grid (16 cm $H_2O$ for < 1 year of age; 18 cm $H_2O$ for ≥ 1 year of age).
      b. HFOV: with $FiO_2$ 1.0 and mPaw > 35 cm $H_2O$
   b. Persistent hypoventilation (pH <7.15)
      c. CMV: with PIP > 32 cm $H_2O$ and a respiratory rate that does not cause intrinsic PEEP (i.e., air trapping)
      d. HFOV: with max power/amplitude at a frequency < 8 Hz

### C. Prone Group

1. Patients assigned to prone positioning will be positioned prone within 4 hours of randomization and will remain prone for at least 16 consecutive hours/day.[25] When supine, patients may be returned prone position ≤ 8H if the $SpO_2$ decreases to <85% for more than 5 minutes.
2. To assure that each group is assessed at the same time each day (10am ± 2 hours), the prone positioned group will be returned supine at 9am ± 2 hours each day.[26] The

[24] Listing is defined as half turns in a patient's position for the purpose of shifting pressure points.
[25] We selected a continuous 16-hour period of prone positioning to remain consistent with the PROSEVA trial.
[26] Thus patients may not be positioned prone for 16 consecutive hours on their first day.

subject's $SpO_2$ will be assessed immediately before and one hour after each supine-to-prone turn each prone-to-supine turn.

3. When subjects less that 8 years of age are prone positioned, the patient's head, upper chest, and pelvis are elevated to allow the abdomen to be unrestrained from the bed.
4. Prone positioning will be accomplished per associated procedure.
   a. Depending on the size of the patient, each turn procedure (supine to prone; prone to supine) will involve 2-4 individuals including the patient's nurse and respiratory therapist.[27] During the turn procedure, one person (usually the respiratory therapist) will be delegated the primary responsibility of ETT protection.
   b. When prone, the subject's head is turned to the side; arms are flexed up; and the lower limbs are cushioned so that the patient's toes are off the bed. The subject's abdomen will not be supported; specifically, rolls will not be used to the elevate the subject's upper chest, and pelvis to allow the abdomen to be unrestrained from the bed.
   c. Prone repositioning includes a cyclic rotation from full prone to right lateral/prone to full prone to left lateral/prone to full prone. When tilted into a lateral prone position, the patient's dependent arm is repositioned against their torso and the non-dependent arm is flexed at the elbow and positioned up towards the patient's head. If the care team believes that the patient cannot tolerate full turns than half turns (listing) will be made every 2 hours to prevent the development of pressure injuries.
5. Unless a change in management is anticipated, procedures that require anterior access to the patient will be accomplished during the 8-hour supine time period.[28] If the care team decides to reposition a patient supine for a procedure during the subject's 16-hour prone period, the site co-investigator must be consulted. The care team and site co-investigator may elect to return the patient prone to complete their daily protocol after an evaluation of the clinical situation.
6. **Criteria for stopping prone positioning**
   a. Improving lung function consistent with resolving PARDS and the subject is close to meeting criteria to be tested for extubation readiness; Specifically, spontaneous breathing and OI < 8 in the supine position for at least 4 hours after the end of the last prone session. After 28 days of prone positioning, all patients who are still intubated can be positioned per the discretion of their care team.
   b. Pattern of no effect where the subject demonstrates a three-day pattern of decreased PF ratio of at least 20%, or an increase in OI of at least 10% post supine-to-prone positioning. If available, documentation of an increase in dead space reflecting a decrease volume of perfused lung after a supine-to-prone turn will be obtained.
7. **Prone positioning will be immediately discontinued in** an emergency: for example, non-scheduled extubation, main-stem bronchus intubation, ETT obstruction, hemoptysis, cardiac arrest, bradycardia or hypotension for more than 5 minutes, and any other life-threatening event.
8. Evolving clinical situations that may also preclude daily PP, that is, acute abdomen or Stage III pressure injury that cannot be managed in the PP.

[27] Two individuals can safely turn an infant, three individuals can safely turn a toddler and young school-aged child, four individuals can safely turn an older school-aged child and adolescent.

[28] Chest films may be obtained in the prone position.

## V. Prone Position Procedure

### A. Preparation for Prone Positioning

1. If < 8 years of age: (Note: No cushioning is required if ≥ 8 years of age.)
   - Create individually sized head, chest, pelvic, distal femoral, and lower limb cushions[29] using egg crate material (Eggcrate; Span American Medical Systems, Greenville, SC) or its equivalent to allow the patient's abdomen to be unrestrained from the patient's bed and to provide skin protection.
     1. The chest cushion should measure: slightly less than the right-to-left greater tubercle of the upper arm; equal the subject's anterior-posterior width; and wide enough to cover the subject's sternum when compressed.[30]
     2. The pelvic cushion should measure slightly smaller than the right-to-left iliac crest and be slightly smaller than the subject's anterior-posterior width.
     3. The head pillow should allow the subject's head to be slightly higher than their chest.
     4. A small cushion should be placed under the distal femur to elevate the subject's knees off the bed.
     5. The lower limb cushion should elevate the subject's toes off the bed.
2. On supine AP CXR, assure that the tip of the ETT is deeper than 1/3 of the thoracic trachea.[31]
3. Assess the security of the endotracheal tube (ETT), vascular lines, and $SpO_2$ probe (by applying gentle traction) and reinforce as necessary. If necessary, re-tape the ETT to the upper lip on the side of the mouth that will end in the "up" position.[32] Place a protective layer of plastic tape over the white adhesive tape holding the ETT.[33]
4. If cuffed ETT/tracheostomy, inflate cuff using minimal leak technique, specifically, inflate cuff until an air leak is auscultated at end-inspiration. Maintain cuff pressure under 25 mmHg.
5. If the patient is receiving neuromuscular blockade, provide eye protection. Specifically, cleanse, lubricate, then covered both eyes with plastic wrap.
6. If the patient is supported on high frequency oscillatory ventilation, apply a transparent film dressing over the anterior surface bony prominences to protect the skin against a friction injury.
7. Move EKG electrodes to the lateral aspects of the upper arms and hips.
8. Remove clothing surrounding thorax and abdomen.
9. Coil then secure bladder catheter to inner thigh.
10. Suction the patient's oropharynx.
11. Temporarily cap nonessential vascular lines and the patient's nasogastric tube. Review the start and end point of all that is left attached to the patient. Arrange the remaining vascular lines and bladder catheter tubing to prevent excessive tension.
12. May provide pre-procedural sedation at the discretion of the nurse caring for the patient.

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[29] Roll loosely and/or cut to appropriate compressed size. Tape along edges to retain shape. Cover egg crate material with pillowcases so that they can easily slide under the patient.

[30] Avoid hyperextension of the patient's shoulder girdle - shoulders should fold into cushion.

[31] Marcano et al. Cephalad movement of tracheal tubes due to PP of pediatric patients with ARDS. CCM 2000; 28(12supp); A31.

[32] To prevent pressure necrosis, the ETT should not be positioned at the corner of the mouth.

[33] Draining oral secretions will loosen the white adhesive tape.

**B. Prone Positioning**

1. The bedside nurse(s)/respiratory therapist team will coordinate the turn.
2. Preplan who will be responsible for what patient aspect (e.g., head/ETT - respiratory therapist; chest/arms – Nurse 1; hips/legs – Nurse 2).
3. Review technique:
   a. Infants/toddlers: levitate up, turn 45 degrees, pause/reassess, turn prone, levitate up to place cushions under the subject.
   b. Children <8 years: using all the bed linens under the subject - slide patient to the edge of the bed away from the ventilator, place new draw sheet over patient; position chest and pelvic cushions over new draw sheet; place new full sheet over entire patient; create a mummy effect by tucking the edges of the full sheet under patient; turn patient 45 degrees toward ventilator, pause/reassess, position patient prone on new linen and cushions/remove old linen.
   c. Children >8 year: using all the bed linens under the subject - slide patient to the edge of the bed away from the ventilator, place new draw sheet over patient; place new full sheet over entire patient; create a mummy effect by tucking the edges of the full sheet under patient; turn patient 45 degrees toward ventilator, pause/reassess, position patient prone on new linen and remove old linen.
4. During the turn keep the patient's head in alignment with their body – avoid hyperextension; contain the patient's arms next to their torso; support the patient's legs so that the toes of the upper leg point in the direction of the turn.
5. Patients are turned toward the ventilator without disconnecting the patient from the ventilator.[34] If the patient must be disconnected from the ventilator consider clamping the ETT using a smooth clamp to avoid the loss of lung volume. If the patient requires ETT suctioning, turning is delayed until the patient is suctioned and has returned to pre-suctioning ventilator settings.[35]
6. Ventilator management: If deemed necessary by the care team, the $FiO_2$ may be manipulated to maintain the target $SpO_2$ during repositioning. All other ventilator settings remain constant until one hour after repositioning. After study blood gases are obtained ventilator settings can be adjusted to achieve target blood gases.[36]
7. Talk the patient through the turn.

**C. Immediately after Prone Positioning**

1. Reassess the security and patency of all tubes/lines.
2. Reassess $SpO_2$, blood pressure cardiac rhythm, breath sounds.
3. Reassess ETT/Tracheostomy air leak; may readjust cuff volume, head position, or delivered Vt to assure adequate ventilation.
4. Uncap/reattach capped off lines/nasogastric tube.
5. Position the patient:
   a. Turn head to side and cushion head and ear with pressure relieving material. Place an absorbent diaper under the patient's mouth to catch draining naso/oropharyngeal secretions.
   b. If < 8 years, avoiding excessive flexion/extension of the spine, cushion the upper chest, and pelvis using either a rolled eggcrate or foam pad - allowing the abdomen

[34] Prevent a loss of lung volume. If patient is disconnected from ventilator than re-recruitment maneuvers may be used to reestablish lung volume.

[35] Extremely important in vulnerable patients who decompensate with multiple procedures.

[36] If the patient is supported on HFOV the care team should anticipate the need to increase the oscillator's power to maintain the same $PaCO_2$ while in the prone position.

to protrude. In adolescent females, check that the breasts/nipples are not pinched. In males, check that the penis and scrotum are unrestrained.

c. Flex arms up.
d. Position knees and feet off bed using a roll under the distal femur and lower leg.
e. Check that everything attached to the patient is not pressing against their skin (e.g., ETT balloon port) and that the patient's skin in not pinched in any way (e.g., peri-umbilical area).

**D. Supine Repositioning**

1. The bedside nurse/respiratory therapist team will coordinate the turn.
2. The precautions and techniques described above apply with the following changes.
3. Consider performing the patient's daily suctioning procedure at hour 14.[37]
4. Patients are turned away from the ventilator without disconnecting the patient from the ventilator.[38]
5. Position the patient:
   a. Cushion head using pressure-relieving materials (pillow, jell pillow).
   b. Elevate the patient's heels off the bed using an appropriate size pillow.

[37] Bronchial drainage may be enhanced while in the prone position.

[38] Prevent a loss of lung volume. If patient is disconnected from ventilator than re-recruitment maneuvers may be used to reestablish lung volume.

## VI. Prone Positioning Check Sheet

| | |
|---|---|
| **Preparation (Prior to getting help into room)** | |
| ❑ | If < 8 years of age: Create cushions using egg crate material (head, chest, pelvic, distal femoral, & lower limb). No cushions necessary if > 8 years of age. |
| ❑ | Check ETT on CXR - tip should be in the lower 1/3 of the thoracic trachea. |
| ❑ | Assess the security of the ETT, vascular lines, $SpO_2$ probe and reinforce as necessary.<br>o Retape the ETT to the upper lip on the side of the mouth that will end in the "up" position.<br>o Place a protective layer of plastic tape over the white adhesive tape holding the ETT. |
| ❑ | If cuffed ETT/trach, inflate cuff using minimal leak technique (cuff pressure under 25 mmHg). |
| ❑ | Protect eyes if chemically paralyzed &/or open (cleanse, lubricate, cover with plastic wrap). |
| ❑ | If HFOV, apply plastic film dressing over anterior bony prominences to avoid friction injury. |
| ❑ | Move EKG electrodes to the lateral aspects of the upper arms and hips. |
| ❑ | Remove clothing surrounding thorax and abdomen. |
| ❑ | Coil then secure bladder catheter to inner thigh. |
| ❑ | Suction the patient's oropharynx.<br>(If ETT suctioned, postpone turn until unit patient returned to pre-suctioning ventilator settings). |
| ❑ | Temporarily cap nonessential vascular lines and the patient's NGT/JT. |
| ❑ | Final Check - Review the start and end point of all that is left attached to the patient. Arrange the remaining vascular lines and Foley catheter tubing to prevent excessive tension. |
| ❑ | Premed with comfort medications at the discretion of the bedside nurse. |
| **Turing (Bedside nurse/RT team.)** | |
| ❑ | Call for RT and at least one other nurse. |
| ❑ | Preplan responsibility: RT - Head/ETT; Nurse 1 - chest/arms; Nurse 2 - hips/legs. |
| ❑ | Review technique:<br>o Infants/toddlers: Levitate = levitate up, turn 45 degrees, pause/reassess, turn prone, to place cushions under the subject.<br>o Children: Mummy = using all bed linens - slide patient to the edge of the bed away from the ventilator, place new draw sheet over patient; (If < 8 years: position chest and pelvic cushions over draw sheet); place full sheet over entire patient; create a mummy effect by tucking the edges of the full sheet under patient; turn patient 45 degrees toward ventilator, pause/reassess, position patient prone on new linen and cushions/remove old linen. |
| ❑ | Keep head in alignment with body, avoid hyperextension, keep arms next to torso, point toes of the upper leg in the direction of turn. |
| ❑ | Turn toward the ventilator without disconnecting. ($FiO_2$ may be manipulated to maintain target $SpO_2$. All other ventilator settings remain constant until 1-hour post turn ABG obtained.) |
| ❑ | Talk the patient through the turn. |

| | |
|---|---|
| **Immediately after the Turn** | |
| ❑ | Reassess the security and patency of all tubes/lines. |
| ❑ | Reassess $SpO_2$, blood pressure, cardiac rhythm, & breath sounds. |
| ❑ | Reassess ETT/Trach leak (May adjust cuff volume, head position, delivered Vt to assure adequate ventilation.) |
| ❑ | Uncap/reattach capped off lines/NGT/NJT. |
| ❑ | Position the patient:<br>o Turn head to side & cushion head and ear with pressure relieving material.<br>o Place an absorbent diaper under the patient's mouth.<br>o If < 8 years: Avoid excessive flexion/extension of the spine. In adolescent females, check that the breasts/nipples are not pinched. In males, check that the penis and scrotum are unrestrained.<br>o Flex arms up.<br>o Position knees and feet off bed using a roll under the distal femur and lower leg.<br>o Check that everything attached to the patient is not pressing against their skin (ETT balloon port) and that the patient's skin in not pinched in any way (peri-umbilical area). |
| **Return to Supine** | |
| ❑ | Precautions & techniques described above apply. |
| ❑ | Consider performing the patient's daily suctioning procedure at hour 14 (2 hours before turn) |
| ❑ | Patients are turned away from the ventilator without disconnecting. |
| ❑ | Position the patient:<br>o Cushion head using pressure-relieving materials (pillow, jell pillow).<br>o Elevate the patient's heels off the bed using an appropriate size pillow. |

## VI. Failed Management

Clinicians may consider a reciprocal therapy (supine to prone; prone to supine; CMV to HFOV; HFOV to CMV) in a sequence based on their clinical judgment while considering ECMO cannulation. Reciprocal treatments, when used, will be managed per *PROSpect* protocols. Subjects cannulated for ECMO will be discontinued from further study treatments and followed so that ventilator management can be described and for study outcomes.

## VII. Hemodynamic Management Guidelines (all groups)

A. Patients will be managed using a fluid conservative strategy, as outlined below.[39]
B. The goal is adequate cardiac output to meet the metabolic needs of the patient, specifically, an acceptable blood pressure for age,[40] brisk capillary refill, and adequate peripheral perfusion to achieve adequate end organ perfusion.
C. The care team will delineate daily mean arterial BP goals.[41]
D. Hypotension, as defined by American Heart Association PALS guidelines,[42] is managed per the shock protocol for resuscitation.
E. If hypotension is not present (may be on dopamine ≤ 5 mcg/kg/min, or epinephrine ≤ 0.03 mcg/kg/min, or any dose of milrinone), determine the appropriate column by evaluating the effectiveness of the circulation. Locate the appropriate instruction box by determining fluid balance (hourly input and urine output).
F. Fluid management in subjects with concurrent acute renal failure are managed at the discretion of the care team.
G. Hemodynamic assessments will be documented at least every four hours. These measurements include systolic blood pressure, urine output/kg/hr, clinical assessment of the effectiveness of the arterial circulation, and central venous pressure (if available). Standard methods for assessing the effectiveness of arterial circulation, that is, capillary refill time, cutaneous "mottling" of the extremities, and core-extremity temperature differences will be used.
H. Fluid Management
    1. Maintenance fluids are calculated per standard pediatric practice.[43]
    2. The care team will determine the type of fluid (colloids, crystalloids) administered.
    3. All fluids, including IV continuous infusions, IV intermittent medications, blood products, IV and enteral nutrition, will contribute to the patient's hourly total. Medications should be administered using the least amount of fluid possible.
    4. Of note, routine pRBC transfusion for a hemoglobin >7 g/dl, without evidence of severe hypoxia, poor tissue perfusion, active bleeding, or hemodynamic instability, is not recommended.
    5. In choosing fluids, ensure normoglycemia.
I. Furosemide is used to achieve desired fluid balance.
    1. Withhold if:
        a. vasopressor or a fluid bolus given in the last 24 hours OR
        b. renal failure present (dialysis dependence) OR oliguria with creatinine 2x upper limit of normal for age OR oliguria with creatinine <2x upper limit of normal for age and urinary studies indicative of acute renal failure.
    2. Begin continuous IV infusion of 0.05 mg/kg/hr (consider 0.5 mg/kg initial bolus) **OR** bolus 0.5-2 mg/kg/dose IV (single suggested max bolus: 20 mg) every 6-12 hours **OR** last known effective dose.
    3. Double continuous infusion hourly, after the first 6 hours, until urine output >0.5

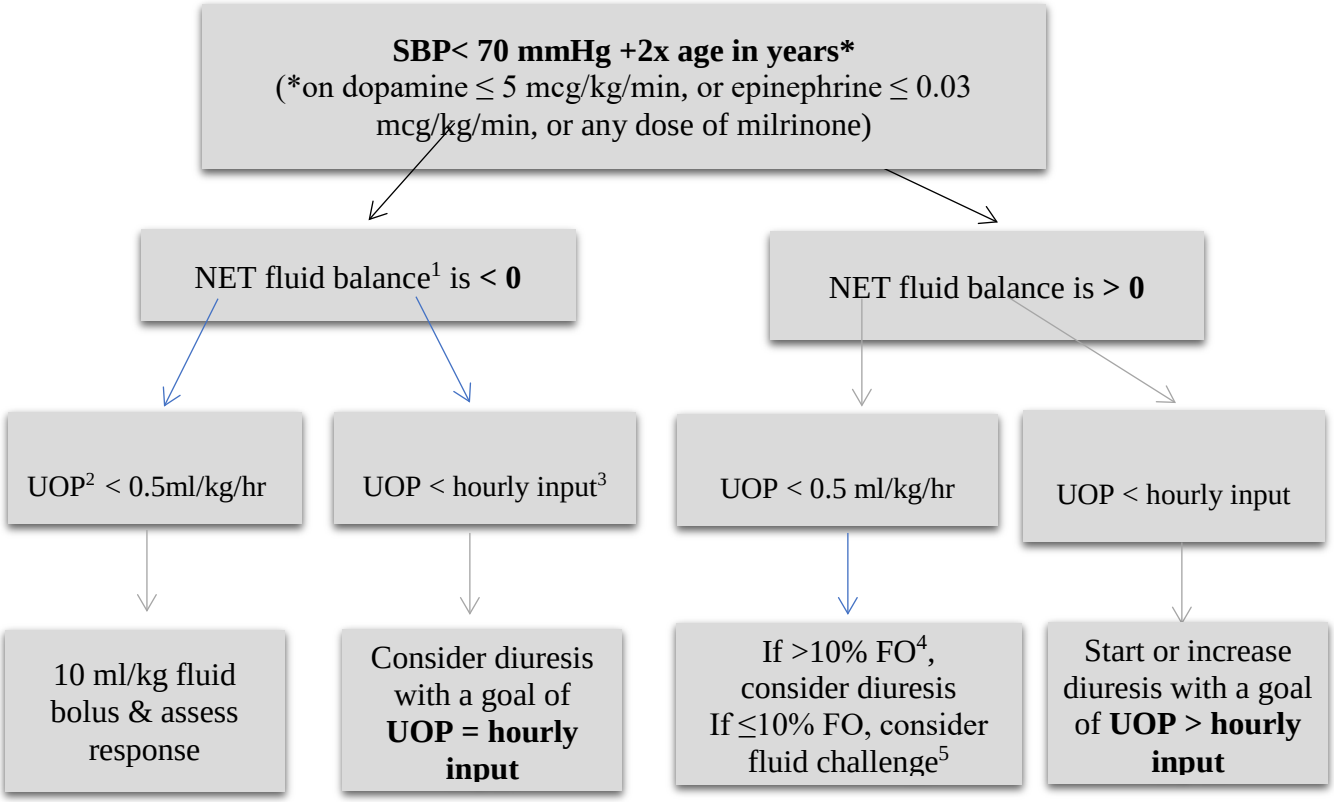
[39] Sections of this protocol were modified from that provided by Stacey Valentine, MD; University of Massachusetts
[40] Blood pressure that is associated with normal lactate, urine output, delta skin-core < 2 degrees C and normal capillary refill.
[41] The use of a central venous catheter is not mandated. CVP includes internal jugular, subclavian or long femoral line in the absence of abdominal pathology. Consider with reproducible waveforms.
[42] Hypotension is defined as a systolic blood pressure <70 mmHg + 2x age in years.
[43] Maintenance fluids universal standard: 100 ml/kg first 10 kg + 50 ml/kg second 10 kg + 25 ml/kg third plus kg.

ml/kg/hour **OR** maximum infusion of 0.5 mg/kg/hr or maximum total daily dose of 8 mg/kg (not to exceed -600 mg/day).

a. Discontinue if:
   1) no response to maximum dose after 1 hour **OR**
   2) intravascular pressure declines to a cell not requiring furosemide therapy.

4. May repeat diuretic trial q 24 hours.
5. The care team may elect to add a second diuretic to achieve the above stated clinical outcomes.

## A. Fluid balance algorithm




[1] **NET fluid balance** = total measured fluids administered to the patient from admission to study randomization (including all nutrition, medications, blood products and intravenous fluids) – total of fluids removed or excreted from the patient (in milliliters) divided by body weight (in kilograms).
[2] **UOP** = urine output as measured in ml/kg/hour. If a Foley catheter is not in place, average each void over the period that elapsed since the previous void.
[3] **Hourly input** = total fluids being given including all continuous infusions, nutrition, intermittent medications and/or blood products.
[4] **Fluid overload** percentage = [(Total intake (L) – Total output (L)) /weight (kg)] x 100%
[5] **Fluid challenge** = 5-10 ml/kg given via push/pull technique with bedside monitoring of HR and BP. If no improvement in HR, consider start of diuresis to augment urine output.

J. Fluid Bolus may be required to reestablish adequate tissue perfusion.
   1. Use 10-15 ml/kg (ideal body weight) normal saline, Ringer's lactate, pRBCs, or albumin. Administer as rapidly as possible then reassess patient. Repeat up to 3 times daily if indicated by protocol.

2. Fluid bolus may be withheld if bolus was given within 24 hours and such bolus did not result in a sustained increase in filling pressure.

K. Inotropes may be necessary to maintain adequate tissue perfusion. Choice at the discretion of the clinical care team.
   1. Dopamine
      a. Start at 5 mcg/kg/min and increase by 5 mcg/kg/min in increments at ~15-minute intervals until ineffective circulation reversed or maximum dose of 20 mcg/kg/min is reached.
      b. Wean by 1-2 mcg/kg/min every 1-2 hours as tolerated, beginning 4 hours after signs of ineffective circulation are reversed.
   2. Epinephrine:
      a. Start at 0.03 mcg/kg/min and increase by 0.02 mcg/kg/min in increments at ~15-minute intervals until ineffective circulation reversed or maximum dose of 0.1 mcg/kg/min is reached.
      b. Wean by 0.01-0.02 mcg/kg/min every 1-2 hours as tolerated, beginning 4 hours after signs of ineffective circulation are reversed.
   3. Milrinone:
      a. Milrinone is administered with a loading dose (optional) followed by a continuous infusion. Volume expanders should be made available to counteract both vasodilator and decreases in filling pressures.
      b. Loading Dose (optional): 50 mcg/kg IV x 1 administered slowly over 20 minutes.
      c. Maintenance Dose: Continuous infusion 0.25-0.75 mcg/kg/min.
   4. Dobutamine
      c. Start at 5 mcg/kg/min and increase by 5 mcg/kg/min in increments at ~15-minute intervals until ineffective circulation reversed or maximum dose of 20 mcg/kg/min is reached.
      d. Wean by 1-2 mcg/kg/min every 1-2 hours as tolerated, beginning 4 hours after signs of ineffective circulation are reversed.

L. Shock Guidelines

   1. Fluid Bolus: Use 20 ml/kg (ideal body weight) normal saline or Ringers Lactate. Administer as rapidly as possible then reassess patient. Repeat bolus at least up to 6 times daily if indicated by protocol.
   2. Vasopressor Therapy: Choice of any single agent or any combination of the following to re-establish and maintain normal blood pressure for age:
      a. Dopamine 5 mcg/kg/min, increase in 2 mcg/kg/min steps q 3-5 min to maximum of 20 mcg/kg/min. (Note: Dopamine <3 mcg/kg/min is not considered a vasopressor.)
      b. Norepinephrine at 0.05 mcg/kg/min, increase in 0.05 mcg/kg/min steps q 3-5 min to maximum of 1 mcg/kg/min.
      c. Epinephrine at 0.05 mcg/kg/min, increase in 0.05 mcg/kg/min steps q 3-5 min to maximum of 0.3 mcg/kg/min.
      d. Phenylephrine at 0.1 mcg/kg/min, increase in 0.1 mcg steps q 3-5 min to maximum of 1.5 mcg/kg/min

## VIII. Sedation Guidelines (all groups)

A. The goals of comfort therapy include analgesia, amnesia, anxiolysis, and compliance with routine care.

B. The patient's level of comfort is assessed per phase of illness and criticality:
   1. Sedation levels will be scored using a valid and reliable pediatric sedation assessment instrument; e.g., the State Behavioral Scale (SBS) or the COMFORT Behavioral Scale at least every 4 hours while intubated.
   2. Pain levels will be scored using an age-appropriate pain scale at least every 4 hours while in the PICU. The pain scale used depends on the patient's age and verbal/cognitive capacity: e.g., the Face, Legs, Activity, Cry, Consolability (FLACC) scale in nonverbal children 0 to 6 years of age, the individualized numeric rating scale (INRS) in nonverbal cognitively impaired children age 6 and older, and the Wong-Baker Faces Pain Scale (WBFPS) in verbal children age 3 and older. All pain scales range 0-10 with higher scores indicating more pain.
   3. In patients receiving neuromuscular blockade, pain/agitation is judged to be present by the bedside nurse when a patient demonstrates a ≥20% increase in heart rate or blood pressure when stimulated.
   4. Delirium screening using either the Cornell Assessment of Pediatric Delirium (CAPD) or the Pediatric or Preschool Confusion Assessment Method for the Intensive Care Unit (pCAM-ICU/psCAM-ICU) will be accomplished at least daily while in the PICU.
   5. Patients weaning from ≥5 days of sedation are monitored for Iatrogenic withdrawal syndrome (IWS) using the Withdrawal Assessment Tool-1 (WAT-1). The WAT-1 scale ranges 0-12 with higher scores indicating more withdrawal symptoms at least Q12 hours.

C. The patient's care team will prescribe a level of sedation/analgesia on daily rounds. Nurses will use a sedation protocol to maintain the patient's level of comfort in the prescribed range.[44] Developmentally appropriate adjunct measures should be utilized whenever possible to help minimize the risks of excessive pharmacological intervention.

D. Centers may substitute drugs within a class (e.g., narcotics - morphine or fentanyl or benzodiazepines - midazolam and lorazepam) and by route of administration (e.g., enteral for intravenous).

E. Patients will receive pre-procedural comfort medications at the discretion of their care team.

[44] See Curley, M.A.Q., Wypij, D., Watson, R.S., Grant, MJ.C., Asaro, L.A., Cheifetz, I.M., Dodson, B.L., Franck, L.S., Gedeit, R.G., Angus, D.C., Matthay, M.A., for the RESTORE Study Investigators and the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network. (2015). Protocolized Sedation versus Usual Care in Pediatric Patients Mechanically Ventilated for Acute Respiratory Failure: A Randomized Clinical Trial. *JAMA, 313(4):379-389*. (PMID: 25602358; PMC4955566)

## IX. Skin Care and Pressure Injury Guidelines (all groups)

A. The goal of therapy is to maintain skin integrity.

B. A daily skin assessment will be performed and recorded on every patient during the acute treatment phase. A Braden QD will be obtained three times per week on Monday, Wednesday and Fridays. After the acute treatment phase, the Braden QD performed and recorded every Wednesday until PICU discharge. Pressure injuries will be staged and managed according to National Pressure Injury Advisory Panel (NPUAP) guidelines.[45]

C. Pressure injuries will be prevented by applying universally accepted prevention strategies. Specifically, patients will be turned (listed) every two hours. Turn schedules will be documented. Specific patient padding will be delineated in the eMOO. All wedges will consist of pressure relieving material.

D. Pressure injuries will require an evaluation by a Skin Care Specialist as soon as possible after identification. In addition to continuing aggressive prevention strategies:
   - Stage I pressure injuries will be treated by the application of a transparent film dressing.
   - Stage II pressure injuries will be treated by the application of a hydrocolloid dressing.
   - Stage III/IV pressure injuries will be treated by the application of either a moist normal saline gauze dressing or calcium alginate dressing under a dry sterile dressing or transparent dressing.

[45] Classify as Stage 1 or 2 or 3 or 4, based on the deepest tissue type exposed. Stage 1 pressure injuries include reversible non-blanchable erythema of intact skin; Stage 2 pressure injuries include partial thickness skin loss involving epidermis and/or dermis; Stage 3 pressure injuries include full thickness skin loss involving damage and necrosis of subcutaneous tissue that may extend down to, but not though, underlying fascia; and Stage 4 include full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures. If the wound base cannot be evaluated, classify as: Deep Tissue Pressure Injury (DTPI) when the skin is intact with deep red, purple or maroon discoloration or blood blister(s) or as Unstageable when the base is obscured by slough or eschar. If on a mucosal membrane, document, but do not stage.

## Appendix 2: Example of Ideal Body Weight (kg) by Length (cm), Gender and Age Weight-for-Recumbent-Length: 2 Weeks to 36 Months

| Recumbent Length (cm) | Weight (kg) | | | Recumbent Length (cm) | Weight (kg) | |
|---|---|---|---|---|---|---|
| | Male | Female | | | Male | Female |
| 45 | 2.29 | 2.31 | | 74.5 | 9.51 | 9.34 |
| 45.5 | 2.39 | 2.40 | | 75.5 | 9.74 | 9.57 |
| 46.5 | 2.59 | 2.61 | | 76.5 | 9.97 | 9.79 |
| 47.5 | 2.80 | 2.82 | | 77.5 | 10.21 | 10.02 |
| 48.5 | 3.02 | 3.04 | | 78.5 | 10.43 | 10.24 |
| 49.5 | 3.25 | 3.26 | | 79.5 | 10.66 | 10.47 |
| 50.5 | 3.48 | 3.49 | | 80.5 | 10.89 | 10.69 |
| 51.5 | 3.72 | 3.72 | | 81.5 | 11.12 | 10.91 |
| 52.5 | 3.96 | 3.96 | | 82.5 | 11.34 | 11.13 |
| 53.5 | 4.21 | 4.20 | | 83.5 | 11.57 | 11.35 |
| 54.5 | 4.47 | 4.45 | | 84.5 | 11.79 | 11.57 |
| 55.5 | 4.72 | 4.69 | | 85.5 | 12.02 | 11.80 |
| 56.5 | 4.98 | 4.94 | | 86.5 | 12.24 | 12.02 |
| 57.5 | 5.24 | 5.19 | | 87.5 | 12.47 | 12.24 |
| 58.5 | 5.50 | 5.44 | | 88.5 | 12.70 | 12.46 |
| 59.5 | 5.76 | 5.70 | | 89.5 | 12.92 | 12.69 |
| 60.5 | 6.02 | 5.95 | | 90.5 | 13.16 | 12.91 |
| 61.5 | 6.28 | 6.20 | | 91.5 | 13.39 | 13.14 |
| 62.5 | 6.54 | 6.45 | | 92.5 | 13.62 | 13.37 |
| 63.5 | 6.79 | 6.70 | | 93.5 | 13.86 | 13.61 |
| 64.5 | 7.05 | 6.95 | | 94.5 | 14.10 | 13.84 |
| 65.5 | 7.30 | 7.20 | | 95.5 | 14.34 | 14.08 |
| 66.5 | 7.56 | 7.44 | | 96.5 | 14.59 | 14.33 |
| 67.5 | 7.81 | 7.69 | | 97.5 | 14.84 | 14.58 |
| 68.5 | 8.06 | 7.93 | | 98.5 | 15.10 | 14.83 |
| 69.5 | 8.30 | 8.17 | | 99.5 | 15.35 | 15.09 |
| 70.5 | 8.55 | 8.41 | | 100.5 | 15.62 | 15.36 |
| 71.5 | 8.79 | 8.64 | | 101.5 | 15.89 | 15.63 |
| 72.5 | 9.03 | 8.88 | | 102.5 | 16.16 | 15.91 |
| 73.5 | 9.27 | 9.11 | | 103.5 | 16.43 | 16.19 |

This chart is an example from the National Center for Health Statistics. Charts used locally should match the norms of the enrolled subject.

## Appendix 3: Example of Ideal Body Weight (kg) by Length (cm), Gender and Age Weight-for-Recumbent-Length: 3-18 Years

This chart is an example from the National Center for Health Statistics. Charts used locally should match the norms of the enrolled subject.

| Recumbent Length (cm) | Weight (kg) | | | Recumbent Length (cm) | Weight (kg) | |
|---|---|---|---|---|---|---|
| | Males | Females | | | Males | Females |
| 86-88 | --- | 12.4 | | 132-134 | 28.4 | 29.4 |
| 88-90 | 13.2 | 12.9 | | 134-136 | 29.8 | 31.0 |
| 90-92 | 13.6 | 13.3 | | 136-138 | 31.2 | 32.4 |
| 92-94 | 14.0 | 13.8 | | 138-140 | 32.7 | 34.1 |
| 94-96 | 14.4 | 14.2 | | 140-142 | 34.3 | 35.6 |
| 96-98 | 14.9 | 14.9 | | 142-144 | 35.7 | 37.0 |
| 98-100 | 15.5 | 15.4 | | 144-146 | 37.5 | 38.1 |
| 100-102 | 16.0 | 16.0 | | 146-148 | 39.1 | 39.2 |
| 102-104 | 16.7 | 16.6 | | 148-150 | 40.7 | 40.7 |
| 104-106 | 17.2 | 17.3 | | 150-152 | 42.3 | 41.8 |
| 106-108 | 17.9 | 17.8 | | 152-154 | 43.6 | 43.3 |
| 108-110 | 18.7 | 18.6 | | 154-156 | 45.4 | 44.7 |
| 110-112 | 19.2 | 19.2 | | 156-158 | 46.7 | 46.0 |
| 112-114 | 20.0 | 19.7 | | 158-160 | 48.1 | 48.1 |
| 114-116 | 20.8 | 20.5 | | 160-162 | 49.4 | 51.4 |
| 116-118 | 21.4 | 21.2 | | 162-164 | 50.8 | 58.2 |
| 118-120 | 22.2 | 22.0 | | 164-166 | 52.1 | --- |
| 120-122 | 23.0 | 22.9 | | 166-168 | 53.9 | --- |
| 122-124 | 23.8 | 23.6 | | 168-170 | 55.6 | --- |
| 124-126 | 24.6 | 24.5 | | 170-172 | 58.1 | --- |
| 126-128 | 25.5 | 25.5 | | 172-174 | 61.1 | --- |
| 128-130 | 26.4 | 26.8 | | 174-176 | 65.2 | --- |
| 130-132 | 27.4 | 28.0 | | 176-178 | 68.9 | --- |

If male height is >178 cm, then IBW (kg) = 50 + 2.3(height in inches - 60);
If female height is >164 cm, then IBW (kg) = 45.5 + 2.3(height in inches - 60).
To convert inches to centimeters, multiply inches times 2.54; to convert centimeters to inches multiply centimeters times 0.4.